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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,272	11/04/2003	R. Scott Twomey	5490-000364	5000
27572	7590	02/22/2006	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			DRYDEN, MATTHEW DUTTON	
		ART UNIT	PAPER NUMBER	3736
DATE MAILED: 02/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/701,272	TWOMEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Matthew D. Dryden	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 November 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 11-16 and 25 is/are allowed.
- 6) Claim(s) 1-10, 17-22 and 24 is/are rejected.
- 7) Claim(s) 23 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 04 November 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)              |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 2 is objected to because of the following informalities: the claim references the distal end, it is unclear what distal end is being referred to, it could be the distal end of the femur, and clarification is necessary. Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 13-26 have been renumbered 12-25.

Because the claims have been renumbered dependent claims must refer back to the proper independent claim number specifically claims 14 and 15 must refer back to claim 12, because of renumbering, claims 18 and 20, must refer back to claim 17, claim 19, must refer back to claim 18, claims 22, 23, and 24 must refer back to claim 21. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Wixon et al (5624444).

Regarding claim 1, Wixon et al disclose a femoral sizing apparatus comprising:  
a block having a face engageable with the distal end of the femur (see around element 16 in Figure 2),  
a body mounted on the block and slidable relative to the block in a medial-lateral direction (the body is slidable on element 33 which is integral to the block portion, the body can be seen around element 22 in Figures 2 and 3),  
a stylus mounted on the body (see around elements 38 and 39 in Figures 2 and 3).

Regarding claim 2, the block comprises a support for engaging a posterior surface of the distal end, see around element 23 in Figure 2).

Claims 17-22, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Antonio (5810831).

Regarding claim 17, D'Antonio discloses a femoral sizing guide comprising:  
a block around element 26 in Figure 2, a face engageable with the distal end of the femur, around element 32 in Figure 2, the block has a base around elements 80 and 84 in Figure 2, and around element 74 in Figure3,  
a body slidably mounted on the base for movement relative to the block in a medial-lateral direction, the body being slid onto the base can be seen in Figure 5,  
a stylus mounted on the body, see around element 44, in Figure 3.

Regarding claim 18,

a channel defined by the base is located below element 84 in Figure 7, and can also be seen around element 70 in Figure 5.

Regarding claim 19,

the channel takes on a U-shape see the elements and Figures as mentioned in the rejection of claim 18.

Regarding claim 20, a face of the block of D'Antonio is capable of engaging a resected surface of the distal end of the femur.

Regarding claim 21, D'Antonio discloses a method comprising:

providing a sizing apparatus having a block, and a body slidably mounted on the block in the medial-lateral direction and a stylus extending from the block and a face engaging the distal femur, see rejection of claims 17-20, above,

selectively sliding the block in a medial-lateral direction, can be found in Columns 5-6, lines 43-3,

moving the stylus to bring a tip of the stylus in contact with an anterior surface of the distal femur and observing an indicator associated with the movement of the stylus, see Column 4, lines 43-62.

Regarding claims 22 and 24, see Column 4, lines 51-62.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wixon et al in view of Eng et al (6056756). Wixon et al discloses the claimed invention except for the block comprising a rod passing through an aperture in the body. Eng et al teaches it is known to provide a femoral tensing and sizing device with a rod (around element 91 in Figure 3) through an aperture of a sizing body (around element 92 in Figure 3), for allowing the stylus body to move up and down so that the vertical height of the femoral surface can be determined (see Column 3, lines 14-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wixon et al with a rod located on a block that passes through an aperture of a body, as taught by Eng et al, for allowing the stylus body to move up and down so that the vertical height of the femoral surface can be determined.

Claims 4, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wixon et al in view of D'Antonio (5810831). Wixon et al discloses the claimed invention except for the lower portion of the body slidably engaging a base of the block.

D'Antonio teaches it is known to provide a femoral sizing guide with a body that is slidably engaged with the base of a block that also includes a U-shaped channel (around elements 84 and 70 in Figures 5 and 7) to ease the addition and removal of the stylus (see Columns 5-6, lines 43-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wixon et al to include the sliding portion of the body to be slidably engaged with the base, as taught by D'Antonio, to ease the addition and removal of the stylus body.

Regarding claim 10, Wixon et al teaches connecting a support to the base to contact a posterior surface of the femur and the support is modularly connected (see column 5, lines 12-51, where the support can be the spacer element 35).

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wixon et al in view of Burkinshaw et al (6290704). Wixon et al discloses the claimed invention except for the stylus being rotatable in the bore (the shaft can be seen around elements 42 and 42a in Figure 3, regarding sliding, see column 6, lines 16-32). Burkinshaw et al teaches a femoral sizing apparatus that includes a stylus that is rotatable within the bore on a body to allow the surgeon to place the tip of the stylus at a preferred location at the various contours of the anterior cortex of the femur (see Column 9, lines 35-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wixon et al to include a rotatably mounted stylus, as taught by Burkinshaw et al, to allow the surgeon to place the tip of the stylus at a preferred location at the various contours of the anterior cortex of the femur.

Regarding claim 6, Wixon et al teaches an arm, element 38 in Figure 3, and a stylus tip, around element 38 in Figure 3.

Regarding claim 7, a window can be seen between element numbers 42a and 22 in Figure 3.

Regarding claim 8, a reading scale adjacent to the window opening can be seen on the top of element 42, by the gradations.

### ***Allowable Subject Matter***

Claims 11-16 and 25 are allowed. The following is a statement of reasons for the indication of allowable subject matter: current femoral sizing devices do not include a U-shaped channel with two pads engageable and a rod extending from the pads in a medial lateral direction, and a body mounted on the rod that includes a bore that has a stylus.

Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Prior Art***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 6,077,270 Katz discloses a method and apparatus for locating bone cuts at the distal condylar femur region to receive a femoral prosthesis and to

coordinate tibial and patellar resection and replacement with femoral resection and replacement

U.S. Pat. No. 5,688,280 Booth, Jr. et al disclose instrumentation for use in orthopaedic surgery

U.S. Pat. No. 5,688,279 McNulty et al disclose an alignment guide for a bone cutting block

U.S. Pat. No. 5,569,261 Marik et al disclose a distal femoral cutting guide apparatus with anterior or posterior referencing for use in knee joint replacement surgery

U.S. Pat. No. 5,720,752 Elliot et al disclose a distal femoral cutting guide apparatus with anterior or posterior referencing for use in knee joint replacement surgery

U.S. Pat. No. 5,662,656 White discloses instrumentation and methods for distal femoral sizing and anterior and distal femoral resections

U.S. Pat. No. 6,096,043 Techiera et al disclose an epicondylar axis alignment and femoral positioning drill guide.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD

  
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